

REMARKS

This Amendment is being filed with a Request for Continued Examination, and is responsive to the rejections maintained from the Final Action and the arguments made in the Examiner's Amendment.

The application has been amended in manner to place it in condition for allowance.

Status of the Claims

Claim 9 is amended to recite the curing time. Support for the newly added features may be found, for example in the paragraph bridging pages 5 and 6.

Claims 1-20 remain in this application.

Claims 1-8, 17 and 18 have been withdrawn from consideration.

Claim Rejections-35 USC §103

Claim 9, 10 and 14 stand rejected under 35 USC 103(a) as being unpatentable over GUYURON et al. 6,471,985 (GUYURON). This rejection is respectfully traversed for the reasons that follow.

The rejection was based on the assumption that GUYURON inherently teaches that the skin surrounding the wound must be covered in order to prevent infection of surgical wounds.

However, there is no support for this assumption in GUYURON.

Several passages from GUYURON were offered to explain why an ordinary artisan would have understood GUYURON's teachings to mean that the silicone composition is applied over a wound, including the surrounding non-wounded skin as is typical of methods to prevent infection by sealing a wound.

It is respectfully submitted that prevention of an infection in a wound can be made in many ways such as the addition of anti-microbial substances, the addition of hydrophobic substances (binding bacteria), the use of hydrophobic material in the dressing, the removal of exudates by drying (high vapor permeability), the absorption of exudates, high oxygen permeability in the dressing and the sealing of the wound. None of these methods typically involves the inclusion of non-wounded skin surrounding the wound.

However, in many cases, the wound pad or the like extends over the wound as well as over non-wounded skin surrounding the wound. This is because it normally is very difficult to adapt the shape of the wound pad or the like to exactly cover only the wound, and it is therefore extended to the surrounding non-wounded skin in order to ensure that the whole of the wound is covered.

With the composition according to GUYURON, however, it is not necessary to extend the composition to the surrounding

skin. Indeed, it is easy to ensure that the whole wound and nothing else is covered independent of the shape of the wound. Thus, with the composition according to GUYURON, there is no need to, for security reasons, let the composition extend beyond the wound onto the surrounding non-wounded skin. A skilled person would have therefore followed the teaching of GUYURON and applied the composition only to the wound.

Indeed, the membrane according to GUYURON is an unique product, i.e., not yet available on the market, which is unlike all wound pads known to one of ordinary skill in the art.

There is no indication in GUYURON that the membrane - in a cured condition - is either self adhering or is adherent to skin. On the contrary, GUYURON discloses that the composition is substantially tack-free about 30 minutes after mixing. A skilled person has therefore no reason to suspect that the composition according to GUYURON is adherent to skin, and thus have no reason to apply the composition according to GUYURON in another way than is stated therein, namely applying it to the wound only.

Moreover, the assumption made in support of the rejection is contradicted by the passage in column 11, lines 6-9 of GUYURON stating that it is an advantage that the composition of GUYURON can be custom fit to any contoured or shaped surface. This advantage is only realized if the composition is to be applied to the wound only and not to the surrounding non-wounded skin.

Thus, a skilled man would apply the composition of GUYURON according to the teaching of GUYURON, i.e., application to the wound only.

In the Examiner's Answer, it was argued that the wording of the claims does not exclude application of the silicone elastomer composition from the wound itself.

However, claim 9 is directed to a method of applying a protective layer to non-wounded skin. Indeed, it is respectfully submitted that application to a wound would be contrary to the teaching of the specification.

It is quite clear that the aim of the invention is to protect non-wounded skin. On page 11, lines 33-37, it is stated "It is important that the layer 3 is applied such that the wound surface is kept free from the preparation in the layer 3 in order to prevent any absorption of exudates in an overlaying dressing." Also from the passage on page 16, lines 30-34, it is quite clear that the preparation should not be applied to the wound itself. The statement that there is no teaching in the specification that the preparation should be excluded from wounded tissue is thus wrong.

The Examiner's Answer also offered two facts (fact 1 and fact 2) in support of the rejection.

Regarding fact 1 on page 13, Applicant respectfully submits that this is incorrect. The viscosity of the uncured composition of GUYURON would make it possible to only cover all

amount of wounded tissue and leave nonwounded skin without composition thereby providing an adequate protection of the wound. The skilled artisan would have understood this possibility and thereby would have applied the composition only to wounded tissue.

Regarding fact 2 on page 14, Applicant understands the term "retain moisture" in GUYURON does not mean that all moisture is retained, but only that the wound be sufficiently wet to enhance wound healing. If the wound is excessively exudating, exudate can leak out on the skin irrespective of if membrane is extended as alleged or only applied to the wound as stated in GUYURON. Since the membrane according to GUYURON is not absorbent, excess of exudates in the wound must leak out onto the skin from the side of the membrane.

It is also respectfully noted that wound infections are often caused by bacteria present on the skin or in the wound itself. Accordingly, if the membrane according to GUYURON is extended beyond the wound edges the risk that bacteria from the skin will enter the wound is increased.

Finally, it was assumed that the composition according to GUYURON was the same as the claimed preparation. However, as evidenced by their respective curing times, they cannot be the same. Indeed, the claimed preparation has a much shorter curing time, i.e., 1 minute to 1 hour as recited in claim 9, than the composition according to GUYURON. GUYURON states, "Typically the

RTV silicone composition is substantially cured at least about 3 hours after application to the wound".

Therefore, for the reasons above, GUYURON fails to disclose or suggest the claimed preparation or the claimed method of applying the preparation. Withdrawal of the rejection is respectfully requested.

Claims 9, 11-13, 15, 16, 19 and 20 stand rejected under 35 USC 103(a) as being unpatentable over GUYURON in view of ABBER et al. 4,925,671 (ABBER). This rejection is respectfully traversed for the reasons that follow.

GUYURON alone fails to disclose or suggest the claimed invention for the reasons mentioned above.

Regarding the combination of GUYURON with ABBER, Applicant respectfully disagrees that it would have been obvious to use the composition of GUYURON as an adhesive for medical devices. As is stated in column 10, 35 - 37 of GUYURON, the composition is substantially tackfree about 30 minutes after mixing. Thus, it cannot be used as a conventional adhesive for medical devices.

Regarding the statement that ABBER's devices are required to have liquid permeability, ABBER only requires that the adhesive shall permit passage of medical liquids therethrough, e.g., claim 1 of ABBER.

ABBER also fails to provide any guidance for modifying GUYURON to reduce the curing time from at least 3 hours to 1 minute to 1 hour.

Therefore, the proposed combination fails to render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

Conclusion

In view of the amendment to the claim and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON

/Robert A. Madsen/
Robert A. Madsen, Reg. No. 58,543
209 Madison Street, Suite 500
Alexandria, VA 22314
Telephone (703) 521-2297
Telefax (703) 685-0573
(703) 979-4709

RAM/jr